UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,045	07/17/2007	Yasuo Suda	247322003800	5627

20872 7590 05/17/2010
MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
05/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,045	SUDA, YASUO	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-8 and 10-12* is/are pending in the application.

4a) Of the above claim(s) *3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, 5, 6-8 and 10-12 are pending of which claims 3 and 5 are withdrawn as being directed to non-elected inventions (see office action of 11/24/09). Therefore, claims 1, 6-8 and 10-12 are examined on merits in this office action.

Claim objections

2. Claim 1 is objected as being in improper Markush format. See MPEP 803.2 for proper Markush type claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925).
3. In claim 1, there is no period at the end of the claim (after the chemical formula). This format does not conform to M.P.E.P 608.01 (m) since each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 6-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being Unpatentable over Sumida *et al* (JP 2003-083969) in view of Nelson *et al* (US

6,756,345 B2) and further in view of either of Yamiya *et al* (JP 2002022745A) or Fazio *et al* (J. Am. Chem. Soc. 2002).

Sumida *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chains having a terminal aromatic amino group is bonded to a biotin terminal (see compound 2). The two hydrocarbon derivative chains branched from nitrogen atom (see compound 5 of the reference) reads on X of claim 1 of instant application. Suda *et al* teach linking sugar ligand (sugar chain) to the amino group attached to benzene ring by reductive amination reaction to prepare compound 5 (paragraph [0120]). Sumida *et al* also disclose that by taking advantage of biotin-streptavidin affinity, compound 5 was arranged on a surface of a sensor chip having streptavidin immobilized thereon to immobilize to the sugar ligand on a surface for analyzing analytes reactive with the sugar ligand by plasmon resonance measurement method.

Sumida *et al* disclose dithilane group attached to one hydrocarbon derivative chain having a terminal aromatic amino group (see abstract) but do not disclose dithiolane group attached to the two hydrocarbon derivative chain having a terminal aromatic amino group. Suda *et al* teach sulfated partial disaccharide (GlcNS6S-IdoA2S) as sugar ligand attached to the linker compound for detection of heparin binding protein (e.g. vWF peptide) in a sample but however, do not mention use of other sugar ligands for detection of other types of analytes.

Nelson et al. disclose a ligand comprising dithiolane group for preparing self-assembled monolayer on metal (e.g. gold) surfaces. The composition provides a highly versatile tethers suitable for immobilization on a metal backbone. Nelson et al. disclose several advantage of using 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) in columns 4-6. One particular advantage is, when bound to metal surface, a 1,2-dithiolane composition of the invention is chemically stable in a wide variety of hostile media and conditions (column 5, lines 1-4). Another advantage cited is that 1,2-dithiolane is thioctic acid, d-thioctic acid (i.e. lipoic acid as disclosed in claim 17 of present application) or derivatives and d-thioctic acid is a natural substance found in mammals and thus are physiologically compatible.

Kamiya *et al* teach sensor surface comprising immobilized sugar chain for detection of toxin by surface Plasmon resonance method and the sugar chain reads on at least one of the compounds represented by R in instant claim 1.

Fazio *et al* teach sugar arrays on a surface for detection of lectins (see abstract) and the sugar chains disclosed (see chart 1 on page 14400) reads on at least one of the compounds of claim 1 represented by R.

Therefore, given the above fact the 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) is advantageous for its stable association with gold surface and is physiologically compatible (Nelson *et al*) and since Sumida *et al* also disclose dithiolane attached to one carbon derivative chain for attachment to gold surface, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute biotin anchoring

group with cyclic –S-S- group (e.g. 1,2-dithiolane, specially lipoic acid) in the tethering residue of Sumida *et al*, with the expectation of obtaining sensor chip stably associated with the linker compound with a reasonable expectation of success. Further, since Kamiya *et al* and Fazio *et al* teach other sugar ligands (sugar chains) useful for detection of other types of analyte, the substitution of the sugar ligand (sugar chain) of Sumida *et al* with another equivalent sugar ligand (sugar chain) as taught by Kamiya *et al* or Fazio *et al* or other commonly know sugar ligands with the expectation of similarly detect other types of analytes in a sample would be obvious to one of ordinary skill in the art absent unexpected results.

With regard to claim 6, the linker compound of Sumida *et al* comprises CH_2 groups.

With regard to claims 7 and 8, Sumida *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chains having a terminal aromatic amino group is bonded to a biotin terminal (see compound 2) for immobilizing linker ligand conjugate to a solid support for protein analysis and a linker compound having a dithiolane group replaced for biotin are obvious in view of Nelson *et al* and the ditholane linker disclosed in the abstract for the reasons as described above.

With regard to claim 11, the branch structure of the compound (5) of Sumida et al reads on m^4, $m^5 = 2$.

With regard to analysis of proteins of claims 10 and 12, since Sumida *et al* teach the method of capturing analytes on a solid support, the use of a

particular know method (as for example, SPR analysis, immunoassay analysis or mass spectrometric method of analysis of bound protein) for analysis of the bound protein is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected result.

6. Claims 1, 6-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al (Tentative Lecture Proceeding, Chemical Society of Japan 2001) in view of Nelson *et al* (US 6,756,345 B2) and further in view of either of Yamiya *et al* (JP 2002022745A) or Fazio *et al* (J. Am. Chem. Soc. 2002).

Hayashi et al. disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chain having a terminal aromatic amino group is bonded to a biotin terminal (see compound 1). Sugar ligand is then linked to amino group attached to benzene ring by reductive amination reaction to prepare compound 2 ligand. Hayashi et al also disclose that by taking advantage of biotin-streptavidin affinity, compound 2 was arranged on a surface of a sensor chip having streptoavidin immobilized thereon. A surface plasmon resonance measurement method for detecting interaction of saccharides with the ligand is also disclosed.

Hayashi *et al* do not disclose using dithiolane anchoring group for attaching the ligand to solid surface such as for attaching to sensor chip surface. However, use of dithiolane for anchoring ligands on solid surface is well known in the art of biosensors. Hayashi et al teach sulfated partial

disaccharide (GlcNS6S-IdoA2S) as sugar ligand attached to the linker compound for detection of heparin binding peptide (e.g. vWF peptide) but however, do not mention use of other sugar ligands for detection of other types of analytes.

Nelson et al. disclose a ligand comprising dithiolane group for preparing self-assembled monolayer on metal (e.g. gold) surfaces. The composition provides a highly versatile tethers suitable for immobilization on a metal backbone. Nelson et al. disclose several advantage of using 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) in columns 4-6. One particular advantage is, when bound to metal surface, a 1,2-dithiolane composition of the invention is chemically stable in a wide variety of hostile media and conditions (column 5, lines 1-4). Another advantage cited is that 1,2-dithiolane is thioctic acid, d-thioctic acid (i.e. lipoic acid as disclosed in claim 17 of present application) or derivatives and d-thioctic acid is a natural substance found in mammals and thus are physiologically compatible.

Kamiya *et al* teach sensor surface comprising immobilized sugar chain for detection of toxin by surface Plasmon resonance method and the sugar chain reads on at least one of the compounds represented by R in instant claim 1.

Fazio *et al* teach sugar arrays on a surface for detection of lectins (see abstract) and the sugar chains disclosed (see chart 1 on page 14400) reads on at least one of the compounds of claim 1 represented by R.

Therefore, given the above fact the 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) is advantageous for its stable association with gold

surface and is physiologically compatible, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute biotin anchoring group with cyclic –S-S- group (e.g. 1,2-dithiolane, specially lipoic acid) in the tethering residue of Hayashi et al, with the expectation of obtaining sensor chip stably associated with the linker compound with a reasonable expectation of success. Further, since Kamiya *et al* and Fazio *et al* teach other sugar ligands (sugar chains) useful for detection of other types of analyte, the substitution of the sugar ligand (sugar chain) of Hayashi *et al* with another equivalent sugar ligand (sugar chain) as taught by Kamiya *et al* or Fazio *et al* or other commonly know sugar ligands with the expectation of similarly detect other types of analytes in a sample would be obvious to one of ordinary skill in the art absent unexpected results.

With regard to claim 6, the linker compound of Hayashi *et al* comprises CH_2 groups.

With regard to claims 7 and 8, Hayashi *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chains having a terminal aromatic amino group is bonded to a biotin terminal (see compounds 1 and 2) for immobilizing linker ligand conjugate to a solid support for analysis of interacting proteins and a linker compound having a dithiolane group replaced for biotin are obvious in view of Nelson *et al* and the ditholane linker disclosed in the abstract for the reasons as described above.

With regard to claim 11, the branch structure of the compounds 1 and 2 of Hayashi et al reads on m^4, $m^5 = 2$.

With regard to analysis of proteins of claims 10 and 12, since Hayashi *et al* teach the method of capturing analytes on a solid support, the use of a particular know method (as for example, SPR analysis, immunoassay analysis or mass spectrometric method of analysis of bound protein) for analysis of the bound protein is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected result.

7. Claims 1, 6-8 and 10-12 are rejected under 35 U.S.C. 103(3) as being unpatentable Arano *et al* (Chemical society of Japan 2002, page 137, 82th Fall Meeting) in view of Sumida *et al* (JP 2003-083969) and further in view of either of Yamiya *et al* (JP 2002022745A) or Fazio *et al* (J. Am. Chem. Soc. 2002).

Arano *et al* disclose a linker compound wherein a branched structure containing three hydrocarbon derivative chains having a terminal aromatic amino group is bonded to a thioctic acid terminal. The three hydrocarbon derivative chains are branched from nitrogen atom (see the abstract). Arono *et al* teach linking sugar ligand (sugar chain) to the amino group attached to benzene ring by reductive amination reaction.

Arano *et al* teach branch structure containing three hydrocarbon chains but do not disclose branch structure containing two hydrocarbon chains branching from nitrogen atom. Arano *et al* teach sulfated partial disaccharide (GlcNS6S-IdoA2S) as sugar ligand attached to the linker compound for detection of heparin binding protein (e.g. vWF peptide) in a sample but

however, do not mention use of other sugar ligands for detection of other types of analytes.

Sumida *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chains having a terminal aromatic amino group is bonded to a sugar ligand (see compound 2). The two hydrocarbon derivative chains branched from nitrogen atom (see compound 5 of the reference). Sumida *et al* also teach one branch structure wherein one hydrocarbon derivative chains from nitrogen atom having terminal aromatic amino group that is bonded to sugar ligand (see abstract).

Kamiya *et al* teach sensor surface comprising immobilized sugar chain for detection of toxin by surface Plasmon resonance method and the sugar chain reads on at least one of the compounds represented by R in instant claim 1.

Fazio *et al* teach sugar arrays on a surface for detection of lectins (see abstract) and the sugar chains disclosed (see chart 1 on page 14400) reads on at least one of the compounds of claim 1 represented by R.

Therefore, given the fact that different number of branch structures with one or two branch chains having terminal aromatic groups are common and known for providing surface immobilized with sugar ligands (Sumida *et al*), branch structure containing two hydrocarbon chains branching from nitrogen atom in the linker compound of Arano *et al* would be obvious to one or ordinary skill in the art absent unexpected results. Further, since Kamiya *et al* and Fazio *et al* teach other sugar ligands (sugar chains) useful for detection of other types of analyte, the substitution of the sugar ligand (sugar chain) of

Sumida *et al* with another equivalent sugar ligand (sugar chain) as taught by Kamiya *et al* or Fazio *et al* or other commonly know sugar ligands with the expectation of similarly detect other types of analytes in a sample would be obvious to one of ordinary skill in the art absent unexpected results.

With regard to claim 6, the linker compound of Arano et al comprises CH_2 groups.

With regard to claims 7 and 8, Arano *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chains having a terminal aromatic amino groups attached to sugar ligands immobilized on a solid support for analysis of interacting proteins and a linker compound comprises dithilane group and as described above linker compound with two branch chains would be obvious in view of the teaching of the branched linker structure of Sumida *et al*.

With regard to claim 11, the branch structure of the compounds of Arano *et al* reads on m^4, $m^5 = 2$.

With regard to analysis of proteins of claims 10 and 12, Arano *et al* teach immobilizing the linker ligand conjugate to a solid support for protein analysis (see abstract) and the use of a particular know method (as for example, SPR analysis, immunoassay analysis or mass spectrometric method of analysis of bound protein) for analysis of the bound protein is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected result.

Response to argument

8. Applicant's arguments and amendments filed 3/1/2010 and terminal disclaimer filed 2/23/2010 have been fully considered, and are persuasive to overcome the rejections under 35 USC 112 second paragraph, 35 USC 101, 35 USC 102, 35 USC 103 and the rejections under obviousness type double patenting. However, Applicants arguments have been rendered moot in view of the new grounds of rejections described in this office action necessitated by Applicant's amendments.

Conclusion

9. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each

amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in ipsis verbis, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641